

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND VENTILATOR PRODUCTS LITIGATION))) Master Docket: Misc. No. 21-)) MDL No. 3014))))) This Document Relates to: All Actions)))))

**SPECIAL MASTER REPORT AND RECOMMENDATION ON
DEFENDANT PHILIPS RS NORTH AMERICA LLC'S MOTION TO
DISMISS THE CONSOLIDATED SECOND AMENDED CLASS ACTION
COMPLAINT FOR MEDICAL MONITORING**

I. INTRODUCTION

Pending in this multi-district litigation arising from the production and sale of certain breathing assistance devices is Defendant Philips RS North America LLC's ("Respironics") Motion to Dismiss the Consolidated Second Amended Class Action Complaint for Medical Monitoring ("MMSAC") for Failure to State a Claim.¹ (ECF No. 1341.) Respironics contends that Plaintiffs have failed to allege present physical

¹ The parties have reached a settlement of the claims in the Third Amended Class Action Complaint for Economic Losses (ECF No. 785). Thus, this Report and Recommendation will not address the claims in that complaint that do not overlap with claims in the MMSAC and will not address Respironics's assertion that Plaintiffs engaged in impermissible claim splitting. Respironics's Motion to Dismiss this argument is now moot and the Court will not address it.

injury as required under a number of jurisdictions' laws. *Id.* at 2.² Respirronics further alleges that Plaintiffs' claims must be dismissed under Fed. R. Civ. P. 12(b)(6) because Plaintiffs have failed to allege significant exposure - a threshold level of exposure sufficient to create an increased risk of future diseases that requires medical monitoring. Supp. Br. (ECF No. 1634) at 21. Regarding Plaintiffs' claims arising under the laws of Colorado, Connecticut, Delaware, Montana, and New Hampshire, Respirronics asserts these claims must be dismissed because medical monitoring is not an independent cause of action under these jurisdictions' laws. *Id.* at 32. With respect to Plaintiffs' claims for declaratory relief, Respirronics asserts they must be dismissed because Plaintiffs' claims are predicated on Respirronics' alleged past conduct which cannot be adjudicated via the Declaratory Judgment Act. *Id.* at 34.

Plaintiffs zealously contest these assertions. The motion has been fully briefed, with Plaintiffs having filed a brief in opposition on March 7, 2023, Respirronics having filed a reply brief on April 21, 2023, and oral argument on the motion being heard on July 11, 2023. *See* Plaintiff's Answering Br. (ECF No. 1634);

² In its Brief in Opposition to Respirronics's motion, Plaintiffs admit that its claims for an independent science panel to determine Plaintiffs' risk of future harm and its claims for jurisdictions in which no plaintiff resides (Alabama, Alaska, Kentucky, Louisiana, Michigan, Mississippi, North Dakota, South Dakota, Wisconsin, and Wyoming), are not justiciable. Opp. Br. (ECF No. 1634) at 28, 38. Thus, this Report and Recommendation will not analyze these claims.

Respironics's Reply Brief (ECF No. 1828); July 11, 2023 Transcript (ECF No. 2130). This decision will address the issues in the same order the parties addressed them at oral argument, beginning with Respironics's assertion that Plaintiffs have failed to plead the elements of a medical monitoring claim.

II. STANDARD OF REVIEW

Defendant's motion primarily relies on Fed. R. Civ. Proc. 12(b)(6) which governs dismissal of an action for failure to state a claim upon which relief can be granted. A court "must accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) [quoting *Philips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)]. To survive a motion to dismiss, a complaint must, at a minimum "state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atlantic Corp v. Twombly*, 550 U.S. 554, 570 (2007). A determination that a complaint demonstrates plausibility "'simply calls for enough facts to raise a reasonable expectation that discovery will reveal evidence of' the necessary elements.'" *Connelly v. Lane Const. Corp.*, 809 F.3d 780, 789 (3d Cir. 2016) [quoting *Philips v. Cnty. of Allegheny*, 515 F.3d 224, 233 (3d Cir. 2008)].

III. WHETHER PLAINTIFFS FAILED TO STATE A CLAIM ABSENT EVIDENCE OF A PRESENT PHYSICAL INJURY

This Report and Recommendation will address each of the parties' arguments in turn, beginning with Respiromics's assertion that Plaintiffs' medical monitoring claims fail under the laws of the majority of jurisdictions because Plaintiffs have failed to allege a present physical injury.

a. Requirement of a Present Physical Injury

Respiromics asserts Plaintiffs have failed to allege a present physical injury, a required element for a medical monitoring claim as adopted in thirty-one jurisdictions. Supp. Br. (ECF No. 1352) at 16. Respiromics recognizes that eleven jurisdictions have recognized an exception to this rule and do not contest Plaintiffs' claims in those jurisdictions for failure to allege a present physical injury.³ *Id.* at 17, n. 9.

In response, Plaintiffs assert they are not required to plead evidence of a present physical injury because they have sufficiently pled an economic injury in the form of the costs of medically necessary diagnostic testing Plaintiffs will need to undergo because of the increased risk of disease caused by their exposure to the PE-PUR foam. Opp. Br. (ECF No. 1634) at 30. Relying on the Restatement (Second) of Torts, Plaintiffs assert that “[t]ortiously-caused present medical necessity to incur

³ The eleven jurisdictions that have amended the traditional rule, and which are not contested by Respiromics on the physical injury requirement, are California, District of Columbia, Florida, Maryland, Missouri, Nevada, Pennsylvania, Utah, Vermont, West Virginia, and Massachusetts. See Citation Table B, Memorandum in Support of Motion to Dismiss (ECF No. 1352).

the cost of diagnostic testing for the early detection of illness or disease constitutes legal detriment and a present injury that does not require proof of present physical injury or diagnosis.” *Id.* at 29. Plaintiffs cite to case law from several jurisdictions to rebut Respiromics’s case law and which Plaintiffs aver recognize that the economic loss associated with diagnostic testing necessitated by another’s tortious conduct is a sufficient injury to support a medical monitoring claim. *Id.* at 31-34.

In sum, Plaintiffs assert that the jurisdictions for which Plaintiffs bring medical monitoring claims fall into three categories that can be treated as subclasses under Fed. R. Civ. P. 23(c)(5). *Id.* at 37. These categories include: (1) jurisdictions that have explicitly addressed and held that a claim for medical monitoring does not require proof of present physical injury (Arizona, California, District of Columbia, Florida, Illinois, Maryland, Massachusetts, Missouri, Nevada, Pennsylvania, Utah, Tennessee, Vermont, and West Virginia); (2) jurisdictions that have not explicitly addressed medical monitoring but would follow Restatement (Second) of Torts §7, recognizing that tortious conduct causing pecuniary loss due to medically necessary diagnostic testing is an invasion of a legally protected interest, and thus, an actual injury under these states’ common law (Arkansas, Colorado, Connecticut, Delaware, Hawaii, Idaho, Indiana, Iowa, Kansas, Maine, Minnesota, Montana, Nebraska, New Hampshire, New Mexico, Ohio, Oklahoma, Puerto Rico, Rhode Island, South Carolina, Texas, Virginia, and Washington); and (3) jurisdictions that have

considered medical monitoring but failed to analyze the injury at issue as economic loss under Restatement (Second) §7, but that would follow Restatement (Second) of Torts §7 and recognize that tortious conduct causing pecuniary loss as being an invasion of a legally protected interest (Georgia, New Jersey, New York, North Carolina, and Oregon).

Respironics argues that acceptance of Plaintiffs' arguments would result in an impermissible expansion of state liability theories by a federal court. Supp. Br. (ECF No. 1352) at 33; *Banks v. E.I. du Pont de Nemours and Co.*, No. 19-1672, 2022 WL 3139087, at *9 (D. Del. Aug. 4, 2022) (dismissing claim for medical monitoring improperly asserted as a standalone cause of action in Delaware where “[t]he Delaware Supreme Court has never recognized medical monitoring as a free-standing tort”). Respironics's argument is compelling. “A federal court in a diversity case is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court” *Day & Zimmermann, Inc. v. Challoner*, 423 U.S. 3, 4 (1975) (per curiam). As explained in *City of Philadelphia v. Lead Industries Ass'n, Inc.*, 994 F.2d 112, 123 (3d Cir. 1993):

A federal court may act as a judicial pioneer when interpreting the United States Constitution and federal law. In a diversity case, however, federal courts may not engage in judicial activism. Federalism concerns require that we permit state courts to decide whether and to what extent they will expand state common law. *See Wisniewski v. Johns-Manville Corp.*, 759 F.2d 271, 274 (3d Cir.1985) (“We leave to ... the state legislatures and, where relevant, to the state courts the task of expanding or restricting

liability for asbestos production.”); *Bruffett v. Warner Communications, Inc.*, 692 F.2d 910, 920 (3d Cir.1982). Our role is to apply the current law of the appropriate jurisdiction, and leave it undisturbed. As the Court of Appeals of the District of Columbia Circuit stated, when it declined to permit a plaintiff to utilize market share liability:

Absent some authoritative signal from the legislature or the [state courts], we see no basis for even considering the pros and cons of innovative theories.... We must apply the law of the forum as we infer it presently to be, not as it might come to be.

Plaintiffs have not contested Respiromics’s demonstration that the highest courts in 31 jurisdictions have not recognized a negligence-based claim for medical monitoring absent physical injury. (See Respiromics’ Citation Table A, ECF No. 1352, at pp. 40-46.) Instead, Plaintiffs invite the Court to find that those jurisdictions would hold that “[t]ortiously-caused present medical necessity to incur the cost of diagnostic testing for the early detection of illness or disease constitutes legal detriment and present injury” sufficient to support an action for medical monitoring. Opp. Br. (ECF No. 1634) at 31. While this argument has intuitive appeal, accepting it for those jurisdictions that have thus far not extended liability in the absence of physical injury is simply a “bridge too far” for a federal court exercising jurisdiction on the basis of diversity of citizenship. Accordingly, it will be recommended that the Court grant Respiromics’s motion to dismiss the medical monitoring claims

asserted under the laws of Arizona,⁴ Arkansas, Colorado, Connecticut, Delaware,⁵ Georgia, Hawaii, Idaho, Illinois,⁶ Indiana, Iowa, Kansas, Maine, Minnesota,

⁴ In *Burns v. Jaquays Mining Corp.* 752 P.2d 28 (Az. App. 1987), the Court distinguished between negligence and nuisance causes of action, holding that a present physical injury *is* required to present a viable claim for medical monitoring based upon the defendant's alleged negligence. The intermediate appellate court observed, “[w]e see no reason to depart from traditional tort concepts and allow recovery for injuries before any disease becomes manifest.” *Id.* at 31. Although the court did recognize that medical monitoring costs could be recovered as part of a nuisance cause of action, Plaintiffs in this matter have not asserted a claim for nuisance.

⁵ On August 26, 2023, the Supreme Court of Delaware, resolving a question certified to it by the U.S. Court of Appeals for the Third Circuit, ruled:

an increased risk of illness without physical harm is not a cognizable injury under Delaware law. Stated differently, an increased risk of harm only constitutes a cognizable injury once it manifests in a physical disease. It is axiomatic that all tort claims require an injury. Under Delaware law, an “injury in fact” is defined as “an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.” An increased risk of illness, without more, is not “actual or imminent,” and thus does not constitute an injury.

Baker v. Croda Inc., No. 393, 2022, 2023 WL 5517797, at *2 (Del. Aug. 24, 2023). In reliance on the Delaware Supreme Court’s ruling the Third Circuit held that “the District Court properly dismissed the Complaint because ‘[t]he class cannot show it has suffered any injury under Delaware law.’” *Baker v. Croda Inc.*, No. 21-3360, 2023 WL 5993109, at *1 (3d Cir. Sept. 15, 2023). Accordingly, it will be recommended that the medical monitoring claim asserted under Delaware law be dismissed.

⁶ The dicta in *Lewis v. Lead Industries Ass’n, Inc.*, 793 N.E.2d 869 (Ill. App. 2003), is not sufficient to support a determination that the Illinois Supreme Court would reject its later holding in *Berry v. City of Chicago*, 181 N.E.3d 679, 688 (Ill. 2020) that an increased risk of harm is not, itself, an injury.”

Montana, Nebraska, New Hampshire,⁷ New Jersey, New Mexico, New York, North Carolina,⁸ Ohio, Oklahoma,⁹ Oregon,¹⁰ Puerto Rico, Rhode Island, South Carolina, Texas, Virginia, and Washington.¹¹

⁷ In *Brown v. Saint-Gobain Performance Plastics Corp.*, --- A.3d ---, No. 2022-0132, 2023 WL 2577257 (N.H. Mar. 21, 2023), the Supreme Court of New Hampshire specifically held that “the mere existence of an increased risk of future development of disease is not sufficient under New Hampshire law to constitute a legal injury for purposes of stating a claim for the costs of medical monitoring as a remedy or as a cause of action in the context of plaintiffs who were exposed to a toxic substance but have no present physical injury.”). Thus, there is no basis for allowing a claim for medical monitoring to proceed under New Hampshire law.

⁸ In *Curl v. Am. Multimedia, Inc.*, 654 S.E.2d 76,81 (N.C. App. 2007), the Court explicitly rejected a medical monitoring claim, explaining that “recognition of the increased risk of disease as a present injury, or of the cost of medical monitoring as an element of damages, will present complex policy questions. We conclude that balancing the humanitarian, environmental, and economic factors implicated by these issues is a task within the purview of the legislature and not the courts.)

⁹ Absent evidence of physical injuries, Oklahoma does not recognize a claim for medical monitoring. *Taylor v. Michelin N. Am., Inc.*, No. 14-CV-293-JED-FHM, 2018 WL 1569495 at *6-7 (N.D. Okla. March 30, 2018).

¹⁰ In *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 187 (Or. 2008), the Oregon Supreme Court held “negligent conduct that results only in a significantly increased risk of future injury that requires medical monitoring does not give rise to a claim for negligence.”)

¹¹ Respiromics, citing, among other cases, *Bostick v. St. Jude Med., Inc.*, No. 03-2636 BV, 2004 WL 3313614, at *14 (W.D. Tenn. Aug. 17, 2004), argues that Tennessee does not recognize an action for medical monitoring in the absence of a present injury. The Court of Appeals for the Sixth Circuit, however, disagreed, concluding that a claim for medical monitoring can proceed even in the absence of a present physical injury. See *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568, 575 (6th Cir. 2005). Based upon the Sixth Circuit’s holding in *Sutton*, it will be recommended that Respiromics’s motion to dismiss the medical monitoring claim under Tennessee law be denied.

b. Massachusetts Law and Subcellular Injury

While conceding that Plaintiffs need not show present physical injury to present a viable claim for medical monitoring under Massachusetts law, Respirronics asserts that the claims under Massachusetts law should nonetheless be dismissed because Plaintiffs have not alleged that their subcellular injuries are established warning signs that Plaintiffs have developed a condition that substantially increases the risk of future illness or disease. Supp. Br. (ECF No. 1352) at 19. In support of this argument, Respirationics relies on the opinion of the Supreme Judicial Court of Massachusetts in *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 901 (Mass. 2009), and on the federal Court opinions in *Genereux v. Hardric Lab'ys, Inc.*, 950 F.Supp.2d 329, 340 (D. Mass. 2013), *aff'd sub nom. Genereux v. Raytheon Co.*, 754 F.3d 51, 53, 55-56 (1st Cir. 2014).

Plaintiffs assert Respirationics improperly reads into the *Donovan* decision a requirement that plaintiffs must demonstrate subcellular change via evidence of detectable biological changes to demonstrate an injury. Opp. Br. (ECF No. 1634) at 37-38. Plaintiffs contend that the court in *Donovan* recognized that evidence of subcellular injury as presented by expert testimony regarding the risks associated with a substance may be sufficient to demonstrate a need for medical monitoring under Massachusetts law. *Id.* at 38. Plaintiffs claim that, by citing *Genereux*, Respirationics incorrectly asserts that Massachusetts has recognized that subcellular

change indicative of a specific future illness is needed to support a claim for medical monitoring. *Id.* Plaintiffs assert Massachusetts has not adopted such a requirement and that the District of Massachusetts merely recognized in *Genereux* that a threat of subcellular change would not be sufficient to demonstrate a claim for medical monitoring. *Id.* In support of their position, Plaintiffs cite to the recall notice Respiromics provided that recognized the toxicity of the PE-PUR foam and the risk of serious injury associated with inhalation of VOCs emitted by the foam. *Id.* (citing MMSAC (ECF No. 815) at ¶ 11).

Contrary to Respiromics's assertion, *Donovan* does not hold that Plaintiffs are required to demonstrate that their subcellular injuries are detectable warning signs of a risk of future illness to obtain medical monitoring. In *Donovan*, when faced with the question of whether plaintiffs who had smoked cigarettes and were exposed to known carcinogens could obtain medical monitoring in the absence of diagnosis, the Massachusetts Supreme Court held that subcellular injuries may not always manifest. 914 N.E.2d at 901. However, the Court recognized that not all cases will involve a physiological change that is a warning sign of a known illness and that "such cases should be allowed to proceed when a plaintiff's reasonable medical expenses have increased (or are likely to increase in the exercise of due care) as a result of these physiological changes." *Id.* The Court went on to recognize a seven-

part test for whether a plaintiff may receive medical monitoring.¹² However, the Court recognized that “[p]roof of these elements usually will require competent expert testimony.” *Id.* at 902.

Respironics relies on portions of the opinion in *Genereux* that relate to the evidentiary showing a plaintiff must make to survive a motion for summary judgment on a medical monitoring claim. 754 F.3d at 56. There, the Court recognized that the plaintiffs’ expert could not confirm that each plaintiff suffered a subcellular injury that established an increased risk of harm like the plaintiffs in *Donovan* suffered. *Id.* Rather, the expert in *Genereux* could only testify that each plaintiff faced a ““significantly increased risk of harm”” from their exposure to beryllium and the First Circuit confirmed the grant of summary judgment in defendant’s favor in light of this evidentiary weakness. *Id.*

The factual circumstances and procedural posture of *Genereux* demonstrate that it would be premature to dismiss Plaintiffs’ claims in reliance on the holding of

¹² “In conclusion, each plaintiff must prove the following: (1) The defendant's negligence (2) caused (3) the plaintiff to become exposed to a hazardous substance that produced, at least, subcellular changes that substantially increased the risk of serious disease, illness, or injury (4) for which an effective medical test for reliable early detection exists, (5) and early detection, combined with prompt and effective treatment, will significantly decrease the risk of death or the severity of the disease, illness or injury, and (6) such diagnostic medical examinations are reasonably (and periodically) necessary, conformably with the standard of care, and (7) the present value of the reasonable cost of such tests and care, as of the date of the filing of the complaint.” 914 N.E.2d at 902.

Genereux at this stage. It is clear expert discovery is needed before this Court can determine whether Plaintiffs have subcellular injuries or merely just increased risks of harm. At this stage, Plaintiffs have sufficiently alleged subcellular injury and an increased risk of serious diseases in a manner that allows their claims to continue to discovery. Plaintiffs allege that Plaintiffs absorbed the toxins into their respiratory tracts and digestive systems where the toxins were absorbed by Plaintiffs' tissue. MMSAC (ECF No. 815) at ¶ 367. Plaintiffs assert that this exposure and ingestion places them at an increased risk of developing a variety of diseases and cite medical studies supporting their contentions that their exposure to the aforementioned toxins places them at an increased risk for disease development. *Id.* at ¶ 368, Section D. At this stage, such pleadings are sufficient and Plaintiffs do not need to demonstrably prove their injuries or risks of harm. Such determinations can only be made following full discovery. Accordingly, it will be recommended that the Court deny Respirronics's motion to dismiss Plaintiffs' claims arising under Massachusetts law.

IV. WHETHER PLAINTIFFS HAVE FAILED TO STATE A CLAIM OF SUFFICIENT EXPOSURE TO HAZARDOUS SUBSTANCES

Relying on the test the Third Circuit established in *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990), Respirronics asserts Plaintiffs have failed to allege (1) the defendant's conduct caused a significant exposure to a known hazardous substance; (2) the exposure substantially increased the risk that Plaintiffs will contract a serious latent disease in the future; (3) periodic diagnostic

examinations exist that make early detection of the serious latent disease possible and reasonably necessary; and, (4) the periodic diagnostic examinations sought are different from the examinations which would be prescribed in the absence of the exposure. Supp. Br. (ECF No. 1352) at 20. In response, Plaintiffs assert they have pled the necessary elements of a medical monitoring claim. Opp. Br. (ECF No. 1634) at 42. Plaintiffs further assert Respiromics suggests a level of detail in the pleadings that is not required to plausibly allege a claim for medical monitoring. *Id.* Relying on the Third Circuit's opinion in *In re Paoli R.R. Yard PCB Litigation*, Plaintiffs assert the expert testimony necessary to prove the elements of a medical monitoring claim are not required at this stage. *Id.*; 916 F.2d at 852. Following review of the parties' papers, relevant case law, and consideration of the parties' presentations at oral argument, the Court finds that Plaintiffs have plausibly alleged a medical monitoring claim sufficient to recommend their claims survive the motion to dismiss stage. The Court will address each element in turn.

i. Plaintiffs have plausibly alleged Respiromics's conduct caused a significant exposure to a known hazardous substance.

First, it is clear, and the parties do not appear to dispute, that Plaintiffs have plausibly alleged that Respiromics's conduct caused exposure to the carcinogens contained in the PE-PUR foam. In the MMSAC, Plaintiffs allege Respiromics used the PE-PUR foam in the Recalled Devices and failed to recall the Devices after Respiromics learned of the degradation issue from customer complaints. *See*

MMSAC (ECF No. 815) at ¶ 228-256. Plaintiffs further allege that Plaintiffs were exposed to harmful substances which Plaintiffs allege place Plaintiffs at an increased risk of developing cancer and other diseases. *Id.* ¶ 484-496. Respiromics does not contest that Plaintiffs have alleged causation. Thus, Plaintiffs have plausibly alleged the first element of a medical monitoring claim.

ii. Plaintiffs have plausibly alleged substantial exposure to a hazardous substance that increased Plaintiffs' risks of contacting serious diseases in the future.

As to the second element, Respiromics asserts Plaintiffs do not plausibly allege that the doses and concentrations they were exposed to in their uses of the Recalled Devices were harmful or increased the risk of contracting a disease in the future. Supp. Br. (ECF No. 1352) at 21. Rather than allege a sufficient dose or concentration to a hazardous substance, Respiromics asserts Plaintiffs merely allege a risk of exposure to hazardous emissions. *Id.* In support of this argument, Respiromics cites to a case from the Southern District of Florida, *Jacobs v. Osmose, Inc.* *Id.*; No. 01-944-CIV, 2002 WL 34241682 at *3 (S.D. Fla. Jan. 3, 2002).

In response, Plaintiffs assert they have alleged significant exposure. Opp. Br. (ECF No. 1634) at 42. First, Plaintiffs assert they have alleged a frequency of use that demonstrates sufficient exposure to the Foam Toxins because each Plaintiff in the class is a user who has used the Devices at least thirty times. *Id.* Second, Plaintiffs assert they have adequately pled exposure to hazardous substances through

the use of the devices. *Id.* Plaintiffs cite to Paragraph 198 of the MMSAC where Plaintiffs rely on the Recall Notice provided by Respiromics which noted:

The absence of visible particles does not mean that foam breakdown has not already begun. Lab analysis of the degraded foam reveals the presence of potentially harmful chemicals including:

- Toluene Diamine
- Toluene Diisocyanate
- Diethylene glycol.

Plaintiffs also refer back the Health Hazard Evaluations published by Respiromics, which noted that the cytotoxicity and genotoxicity testing demonstrated that “a reasonable worst-case estimate for the general and higher risk (e.g., patient populations with preexisting conditions or comorbidities) patient population is a severity level 3 (Crucial) for both short/intermediate and long term exposure.” *Id.* at ¶ 203.

The allegations of the MMSAC satisfy the second element of the test for medical monitoring. Plaintiffs allege that they were exposed to substances that are known and likely carcinogens, including toluene diamine, toluene diisocyanate, diethylene glycol, dimethyl diazine, and formaldehyde. *See* MMSAC (ECF No. 815) at ¶ 198. Moreover, Plaintiffs cite studies establishing the hazardous nature of these substances. At this stage, Plaintiffs have sufficiently alleged the hazardous nature of these substances to survive Respiromics’s motion to dismiss.

Respironics does not allege a specific level of exposure which Plaintiffs should have alleged to plausibly allege substantial exposure. A review of the Citation Table provided by Respiromics demonstrates that a common element of showing exposure is that a plaintiff has been exposed to the substance at a level that exceeds the exposure the plaintiff would have been exposed to absent the defendant's conduct. This level of exposure aligns with the Third Circuit's prior interpretation of this element under Pennsylvania law. *Barnes v. American Tobacco Co.*, 161 F.3d 127, 139 (3d Cir. 1998).

Respironics cites *Riva v. Pepsico*, 82 F.Supp.3d 1045, 1050 (N.D. Cal. 2015), as support for its argument that Plaintiffs have failed to allege the toxicity of the substances. Supp. Br. (ECF No. 1352) at 26. There, the court dismissed the plaintiffs' claims for failure to demonstrate that they were exposed to a substance in sufficient level to warrant medical monitoring. 82 F.Supp.3d at 1050. But the substance at issue in *Riva* had only been shown to create an increased risk of cancer in laboratory animals and plaintiffs did not demonstrate that a similar harm would result from significant exposure to humans. *Id.* at 1057. This is in contrast to the assertion here, where Plaintiffs cite to several studies concluding that a similar harm observed in animal testing would result from significant exposure by humans. MMSAC (ECF No. 815) at ¶¶ 212, 215, 218, 219, 221, 224, 227.

The facts of *In Re Zantac (Ranitidine Prod. Liab. Litig.)* are similarly distinguishable. 546 F.Supp.3d 1152, 1171 (S.D. Fla. 2021). There, plaintiffs asserted that they regularly ingested ranitidine products that contained active ingredients that could transform into a cancer-causing molecule called N-nitrosodimethylamine (“NDMA”). *Id.* at 1160. In analyzing the defendant’s motion to dismiss the plaintiffs’ medical monitoring claims and after undertaking a detailed review of the plaintiffs’ scientific studies, as well as performing its own calculations, the court held that plaintiffs had failed to allege a degree of exposure that would result in an increased risk of cancer. *Id.* at 1171. Following detailed review of the plaintiffs’ cited studies and conducting its own analysis, the Court held that the plaintiffs had failed to allege the amount of NDMA exposure contained in a dose of the ranitidine products and failed to allege the number of doses plaintiffs had consumed. *Id.* at 1174-76. In coming to this decision, the court noted that even if it based its plausibility assessment on the studies cited by plaintiffs, it could not find plaintiffs had alleged a claim for medical monitoring because plaintiffs failed to allege the frequency with which plaintiffs consumed the product. *Id.* at 1175.

The facts of *Lafferty*, which Respiromics cites in its papers and highlighted during oral argument, are similarly distinguishable. *Lafferty v. Sherwin-Williams Company*, No. 1:17-06321-RBK/AMD, 2018 WL 3993448 at *5 (D.N.J. Aug. 21, 2018). There, plaintiffs sought to recover for environmental exposure to lead and

arsenic but failed to allege personal exposure, the specific disease plaintiffs were at an increased risk for, and the type of medical monitoring program that would be necessary to detect the diseases. *Id.* at *5. Plaintiffs here allege both exposure to specific toxic substances and allege they may develop a host of specific diseases and conditions as a result of that exposure. MMSAC (ECF No. 815) at ¶¶ 212, 215, 218, 219, 221, 224, 227, 371.

The facts of *In Re Zantac (Ranitidine Prod. Liab. Litig.)* also distinguish it from this case. First, in *In Re Zantac* involved a medication that had quantifiable ingredients from which a calculation could be made as to the likely NDMA exposure a plaintiff received in a single dosage. *Id.* at 1172. Here, by way of contrast, Plaintiffs cannot perform similar calculations due to the nature of the degradation and off-gassing. The level of detail Respiration seeks would require Plaintiffs to have alleged the degree of degradation present in their own machines, which as Plaintiffs highlight, would have required Plaintiffs to open and inspect their Devices against Respiration's clear recall instruction to avoid opening the Devices. Opp. Br. (ECF No. 1634) at 45. Moreover, to require Plaintiffs to perform such testing and develop such calculations prior to discovery would be overly burdensome. Second, whereas the plaintiffs in *In Re Zantac* merely alleged plaintiffs ingested "therapeutic dosages" of the drug without allegations of frequency, Plaintiffs here allege they

each used the Recalled Devices at least thirty times. MMSAC (ECF No. 815) at ¶ 387. Thus, the support plaintiffs lacked in *In Re Zantac* is present here.

To require Plaintiffs to plead with scientific specificity the necessary levels of exposure from off-gassing would unnecessarily foreclose Plaintiffs' claims despite evidence of exposure to hazardous substances that Plaintiffs have plausibly alleged lead to an increased risk of harm. Although Respiromics seeks more specific allegations regarding the measurable amount of toxins Plaintiffs were exposed to in the use of the Devices, this level of specificity is not required on a motion to dismiss. Such calculations will undoubtedly depend upon expert testimony and should be left for discovery, after which Respiromics may reassert its arguments at summary judgment. The specifics of whether Plaintiffs' exposures and increased risks of harm must be developed on a full factual record. At this stage, Plaintiffs have plausibly alleged enough information to continue to discovery.

Respiromics asserts that because of Plaintiffs' failure to allege how many hours on average each Plaintiff used the Recalled Devices, Plaintiffs have failed to show exposure beyond the average public's exposure to these substances. Supp. Br. (ECF No. 1352) at 27. Respiromics's reliance on *Rutigliano v. Valley Business Forms*, 929 F. Supp. 779, 790-92 (D.N.J. 1996), to assert that Plaintiffs are exposed to formaldehyde in daily life is misplaced. In *Rutigliano*, the court's discussion of formaldehyde in modern life was limited to assessment of whether an expert's report

was sufficiently thorough to be relied upon under *Daubert*. 929 F. Supp. At 790-92. Thus, the holding is not dispositive in determining whether Plaintiffs were exposed to formaldehyde in an excessive level through the Recalled Devices. Plaintiffs allege inhalation of the air produced by the Devices containing PE-PUR that could, by Respiromics own admission in its Recall Notice, degrade without noticeable change. Plaintiffs have thus plausibly alleged significant exposure to harmful substances that are likely to cause future health conditions.

Respiromics's contention that Plaintiffs' claims fail because their Complaint incorporated studies showing there was a less significant risk of exposure than initially believed is also not dispositive. Unlike those cases which Respiromics relies on, the studies here recognized there was at least a small risk that users would be exposed to PE-PUR foam through degradation, a fact Respiromics itself admits. Thus, it would be difficult to determine that the studies "simply do not support the allegations" as Respiromics asserts, when a likelihood of degradation, albeit small, was found. Further, analysis of the studies would require an assessment of the weight that should be granted to these studies, a task which the courts in the cases cited by Respiromics held to be inappropriate on a motion to dismiss. *See Sabol v. Bayer Healthcare Pharm, Inc.*, 439 F.Supp.3d 131, 148 (S.D.N.Y. 2020) ("Of course, 'issues of fact, credibility and the weight of evidence' -- including how much

weight should be accorded to publications and other scientific studies are not properly considered on motion to dismiss.”).

iii. Plaintiffs have plausibly alleged diagnostic examinations will make early detection possible and reasonably necessary.

Respironics’s assertion that Plaintiffs fail to identify specific diseases for which they are at risk as a result of their exposures to the aforementioned toxins is unfounded. While Respiration correctly asserts that the Eastern District of Pennsylvania recognized in *Slemmer v. McLaughlin Spray Foam Insulation, Inc.*, No. 12-6542, 2013 WL 5655480 at *3 (E.D. Pa. Oct. 17, 2013), that merely pleading that Plaintiffs were at heightened risk for “lung damage, and throat, eye and nose irritations” was insufficient, Plaintiffs provided significantly greater detail here.

In Paragraph 368 of the MMSAC, Plaintiffs allege:

It has been widely accepted for decades that certain of the Foam Toxins (specifically formaldehyde, DEG, and DD’s precursor and successor compounds) are toxic and/or carcinogenic to humans. For decades, scientific literature and regulatory agencies around the world have made clear that exposure to the Foam Toxins causes various adverse health effects, including Case 2:21-mc-01230-JFC Document 815 Filed 10/17/22 Page 150 of 222 137 cancers. 409 Moreover, the synergistic effects of having multiple toxic and carcinogenic materials in the body at the same time likely compound the adverse health outcomes.

Paragraph 371 alleges:

based on available scientific literature, exposure to the Foam Toxins places Plaintiffs and Class members at increased risk of developing a number of serious illnesses and diseases, including but not limited to the following: cancer, including cancer as of the head, neck, kidneys, liver, brain, pancreas, blood-forming tissue,

respiratory system, gastrointestinal system, reproductive system, and lymphatic system; respiratory diseases such as asthma, chronic bronchitis, chronic obstructive pulmonary disease, constrictive bronchiolitis or obliterative bronchiolitis, emphysema, interstitial lung disease, pleuritis, pulmonary fibrosis, sarcoidosis; and chronic sinusitis, chronic rhinitis, and other forms of chronic inflammation. The Foam Toxins are cytotoxic and genotoxic; as such, exposure causes widespread damage to DNA as well as the reproductive system, neurological system, and other critical systems.

Here, Plaintiffs allege that they are at risk for specific types of cancer and respiratory complications. Thus, Respirationics is sufficiently put on notice regarding the types of claims it will need to defend against.

iv. Plaintiffs have plausibly alleged the frequency of the periodic diagnostic examination.

The Third Circuit has generally held that Plaintiffs cannot recover medical monitoring for treatments that would be recommended for the general population, such as annual physicals and cardiovascular assessments. *Barnes v. American Tobacco Co.*, 161 F.3d at 155. However, Respirationics fails to recognize that in *Barnes* the assessment of whether a plaintiff would normally receive the type of diagnostic testing at issue depended upon additional discovery regarding the plaintiff and his or her health. *Id.* (noting discovery revealed plaintiff to be a smoker who would be recommended to have regular diagnostic testing).

To the extent Respirationics relies on *Slemmer*, the Court finds that Plaintiffs' request for medical monitoring exceeds the bare-bones request in *Slemmer*. No. 12-6542, 2013 WL 5655480 at *3. There, plaintiffs merely requested a medical

monitoring regime consisting of “diagnostic tests and pharmaceutical interventions.”

Id. When given the opportunity to amend, the plaintiffs failed to allege additional specificity and merely requested “diagnostic exams and pharmaceutical interventions” to “prevent or mitigate” the alleged injuries. *Id.* Here, Plaintiffs provide sufficient detail to demonstrate diagnostic monitoring that would detect any illness. In Paragraph 493 of the MMSAC, Plaintiffs specifically request:

blood and laboratory tests; physical examinations; imaging; colonoscopies; endoscopies; and other similar methods for examination; biopsies; pathologic, histologic, and oncologic evaluations; and oncologic, histologic, surgical, and other necessary medical evaluations.

Although Respirronics asserts Plaintiffs have not alleged this requested diagnostic testing will definitively demonstrate any particular disease, there is no indication exposure to the PE-PUR foam will result in a signature disease. Relying on cases addressing signature diseases, including asbestosis and chronic beryllium disease, Respirronics asserts these tests are no different than testing Plaintiffs would have received in the absence of exposure. To follow this logic would foreclose Plaintiffs’ claims because they are not at risk for a signature disease which has an accepted diagnostic and interventional treatment program. At this stage, it will not be recommended to limit Plaintiffs’ claims in this way.

Further, Plaintiffs correctly assert that the Southern District of Florida has agreed that the question of whether the type of medical monitoring was an issue of

fact and has approved claims for generalized “baseline tests and periodic diagnostic examinations.” *In re Zantac (Ranitidine) Products Liability Litigation*, 546 F.Supp.3d 1152, 1168 (S.D. Fla. 2021). There, the Court permitted Plaintiffs’ request for otherwise common diagnostic testing because Plaintiffs alleged in their complaint that their injuries “require specialized testing . . . that is not generally given to the public at large” and “different from that normally recommended in the absence of exposure to this risk of harm” *Id.* Here, Plaintiffs do not allege that Plaintiffs will need specialized testing but recognize that Plaintiffs will likely need “more frequent screenings not in the purview of routine medical exams.” MMSAC (ECF No. 815) at ¶ 496.

Plaintiffs’ assertion that they will need more frequent medical testing than is currently provided for the general population satisfies *Barnes*. The frequency of medical testing Plaintiffs may require distinguishes the testing Plaintiffs request from the tests the public would receive absent exposure under the fifth element of a medical monitoring claim. Accordingly, Plaintiffs have plausibly alleged that they will require greater testing than the average population as a result of Respiromics’s actions.

Accordingly, it will be recommended that the Court deny Respiromics’s motion to dismiss the Second Amended Medical Monitoring Claim for failure to state the elements of a medical monitoring claim.

V. WHETHER PLAINTIFFS HAVE FAILED TO STATE AN INDEPENDENT CAUSE OF ACTION UNDER THE LAWS OF THE CLAIMED JURISDICTIONS

Respironics asserts that five states have not recognized medical monitoring as an independent cause of action: Connecticut, Colorado, Delaware, Montana, and New Hampshire. Having already recommended that the Court grant Respiration's motion to dismiss the claims for medical monitoring under the laws of these jurisdictions, this Report not address the question at any greater length.

VI. WHETHER PLAINTIFFS HAVE FAILED TO STATE A CLAIM FOR DECLARATORY JUDGMENT

Respironics asserts Plaintiffs' claim for declaratory relief must be dismissed because Plaintiffs seek to recover for past conduct relating to the Recalled Devices, conduct which Respiration asserts cannot be adjudicated via a declaratory judgment. Supp. Br. (ECF No. 1352) at 34. In response, Plaintiffs assert that their harm from Respiration's past conduct is ongoing and will continue into the future, rendering the past conduct subject to a declaratory judgment. Opp. Br. (ECF No. 1634) at 49. Because it does not appear that declaratory relief would be academic, it will be

recommended that the Court deny Respiromics's motion to dismiss the Fifteenth Claim for Relief, the request for a declaratory judgment.

VII. WHETHER PLAINTIFFS HAVE FAILED TO STATE A CLAIM UNDER STATES' PRODUCTS LIABILITY ACTS

Respiromics asserts that Plaintiffs' claims under the products liability acts of Connecticut, Indiana, Kansas, New Jersey, Ohio, Tennessee, and Washington must be dismissed because these states require Plaintiffs to allege a manifest personal injury and no Plaintiff alleges such an injury. Respiromics's Motion to Dismiss (ECF No. 1351) at vii; Supp. Br. (ECF No. 1352) at 35. In response, Plaintiffs assert that they plead twin harms sufficient to meet the harm requirements of these jurisdictions: (1) a present and ongoing economic injury in the need to incur the cost of medical monitoring for early detection of disease due to their exposure to the Foam Toxins, ¶ 375 and (2) "subcellular injury or other physiological changes that create and/or increase the risk that Plaintiffs will develop cancer and other diseases" caused by Plaintiffs' use of the Recalled Devices. MMSAC (ECF No. 815) at ¶ 25-88, 733; Opp. Br. (ECF No. 1634) at 52. Plaintiffs assert these allegations exceed the requirements of the statutes at issue, relying on *In re Valsartan, Losartan, & Irbesartan Prods. Liab. Litig.*, MDL No. 2875, 2021 WL 364663 at **12-14, 17-20, 24-27 (D.N.J. Feb. 3, 2021) (denying motion to dismiss medical monitoring claims under the New Jersey, Connecticut, Indiana, Kansas, Ohio, Tennessee and Washington products liability acts when Plaintiffs alleged "cellular damage, genetic

harm, and/or an increased risk of developing cancer” resulting from exposure to carcinogens in blood pressure medication).

Upon review of the parties’ briefing and independent research, it is recommended that the Court deny Respiromics’s motion to dismiss the statutory claims arising under the products liability acts of Connecticut, Indiana, Kansas, New Jersey, Ohio, Tennessee, and Washington.

i. Connecticut

Relying on *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769 (Conn. 2003), Respiromics asserts that Plaintiffs have failed to state a claim for medical monitoring because Plaintiffs fail to allege a present physical injury. Supp. Br. (ECF No. 1352) at 36. Section 52-572m of the Connecticut General Statutes provides that a “product liability claim” falling within the ambit of the statute includes “all claims or actions brought for personal injury, death or property damage caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging or labeling of any product.” Conn. Gen. Stat. § 52-572m. Plaintiffs assert Respiromics misconstrues the definition of harm under the Connecticut Products Liability Act., Conn. Gen. Stat. Ann. §52-572m-q. Plaintiffs assert the statute defines harm as including “the product itself, and personal injuries including wrongful death” which Plaintiffs meet by pleading economic injury and subcellular injury. Opp. Br. (ECF No. 1634) at 53-54. Plaintiffs further

allege *Gerrity* is inapplicable because it addresses wrongful death and does not address the minimum threshold of injury under the CPLA. *Id.*

Gerrity addressed whether the plaintiff could bring separate claims under the Connecticut Unfair Trade Practices Act and the Products Liability Act. The Court determined that the claim for “financial injury . . . cannot be reasonably construed to be a claim for ‘personal injury, death or property damage’” under the Products Liability Act. 818 A.2d at 776. Therefore, the plaintiff could bring the action under the CUTPA in conjunction with a separate action under the Products Liability Act. *Id.* Other cases interpreting Section §52-572m-q of the Products Liability Act do not clearly address the question presented and focus on physical injuries caused by products. *Collazo v. Nutribullet*, 473 F.Supp.3d 49 (D. Conn. 2020); *Fisher v. McDonald’s Corp.*, 810 A.2d 341 (Sup. Ct. Conn. 2002).

Here, Plaintiffs’ medical monitoring claims for recovery under the CPLA are based upon “harm” caused by the Recalled Devices. Accordingly, it will be recommended that the motion to dismiss the claim presented under the CPAL be denied.

ii. Indiana

In support of its argument that Plaintiffs’ claims arising under Indiana law must be dismissed, Respiration relies on *DeVane v. Arch Wood Protection Inc.* to assert that Plaintiffs’ claims for risk of future physical harm is insufficient to state a

claim for harm. 197 N.E.3d 343, 347 (Ind. App. 2022); Supp. Br. (ECF No. 1352) at 36. Plaintiffs contend *DeVane* is inapposite because it does not address a products liability claim and assert that the Indiana Products Liability Act, Ind. Code §§34-20-1-1-9-1, does not require “physical or personal injury” or a “manifest personal injury” but merely requires a showing of physical harm, defined as “bodily, injury, death, loss of services, and rights arising from any such injuries.” Opp. Br. (ECF No. 1634) at 57. Plaintiffs also assert that the Indiana Appeals Court has recognized that a plaintiff can recover for medical monitoring absent evidence of a present physical injury. *Id.* at 58; *Gray v. Westinghouse Elec. Corp.*, 624 N.E.2d 49 (Ind. App. 1993); *Allgood v. General Motors Corp.*, No. 102CV1077DFHTAB, 2005 WL 2218371 at *7 (S.D. Ind. Sep. 12, 2005).

In *DeVane*, the court recognized that a products liability claim arising under Indiana law must allege that the plaintiffs suffer from an existing physical harm. 197 N.E.3d at 346-47. Plaintiffs have alleged a physical injury in the Second Amended Medical Monitoring Complaint in the form of subcellular damage and physiological injuries sufficient to give rise to a claim under the Indiana Products Liability Act. Accordingly, it will be recommended that the Court deny Respirationics’s motion to dismiss Plaintiffs’ claims arising under the Indiana Products Liability Act.

iii. **Kansas**

Relying on the Kansas Supreme Court's opinion in *Fennesy v. LBI Mgmt. Inc.*, 847 P.2d 1350, 1354 (Kan. 1993), Respiromics asserts that Plaintiffs' claims arising under Kansas law must be dismissed. Supp. Br. (ECF No. 1352) at 36. Plaintiffs assert that Respiromics misreads the Kansas Products Liability Act, K.S.A. 60-3301, which defines harm as "(1) damage to property; (2) personal physical injuries, illness, and death; (3) mental anguish or emotional harm attendant to such personal physical injuries, illness or death" and limits harm to exclude "direct or consequential loss." Opp. Br. (ECF No. 1634) at 56. Plaintiffs assert their allegations of a subcellular injury meet this standard and that *Fennesy* does not read a manifest physical injury requirement into the statute. *Id.*; 847 P.2d 1250, 1354 (Kan. 1993). Plaintiffs offer *Burton v. R.J. Reynolds Tobacco Co.*, 884 F. Supp. 1515, 1522-23 (D. Kansas 1995) in support of its arguments. Opp. Br. (ECF No. 1634) at 57.

Fennesy concerns the application of the statute of limitations. In the portion Respiromics relies on, the court quotes the language of the products liability act to recognize that "The KPLA applies to product liability claims involving damage to property, personal physical injuries, and attendant mental anguish or emotional harm." *Id.* at 1354. However, there is no analysis of the physical injury requirement. In the case cited by Plaintiffs, *Burton v. R.J. Reynolds Tobacco Co.*, the Court

recognized that medical monitoring is appropriate where “the plaintiff has sustained an injury.” 884 F. Supp. at 1523. Under these circumstances, it will be recommended that the Court deny Respiromics’s motion to dismiss Plaintiffs’ claims arising under the KPLA.

iv. New Jersey

Respiromics generally avers that in *Sinclair v. Merck & Co.*, 948 A.2d 587 (N.J. 2008), the New Jersey Supreme Court held that the New Jersey Products Liability Act (“NJPLA”), N.J. Stat. §§2A:58C-1-7, required Plaintiffs to “allege and prove a manifest personal injury to recover medical monitoring expenses.” Supp. Br. (ECF No. 1352) at 35. Plaintiffs assert Respiromics misconstrues that text of the NJPLA. Opp. Br. (ECF No. 1634) at 52-53. Because Plaintiffs have alleged physical injury in the form of physiological changes and subcellular harm, it will be recommended that the Court deny Respiromics’s motion to dismiss Plaintiffs’ claims arising under the NJPLA.

v. Ohio

Under the Ohio Products Liability Act (“OPLA”), Ohio Rev. Code Ann. §§ 2307.71-2307.80, harms are defined as “death, physical injury to person, serious emotional distress, or physical damage to property other than the product in question,” and does not require a “manifest physical injury” as Respiromics asserts. Further, Plaintiffs cite *Elmer v. S.H. Bell Co.*, 127 F.Supp.3d 812, 825 (N.D. Ohio

2015), for the proposition that “[a] plaintiff is not required to demonstrate physical injuries in order to obtain medical monitoring relief.” Opp. Br. (ECF No. 1634) at 55.

In *Day v. NLO*, the Southern District of Ohio recognized that prospective medical monitoring is an appropriate form of relief where liability has been established in cases addressing a disease with “a protracted latency period, which may not manifest itself for many years.” 851 F. Supp. 869, 880 (S.D. Ohio 1994). Under these circumstances, it will be recommended that the Court deny Respiromics’s motion to dismiss Plaintiffs’ claims arising under the Ohio Products Liability Act.

vi. Tennessee

Plaintiffs assert Respiromics reads into the requirements of the Tennessee Products Liability Act, Tenn. Code Ann. §§29-28-101 a limitation that does not exist. Opp. Br. (ECF No. 1634) at 55-56. Plaintiffs assert the statute allows claims asserting harm in the forms of “. . . personal injury, death or property damages” and does not require “manifest personal injury” as Respiromics claims. *Id.* Plaintiffs assert the case cited by Respiromics, *City of Franklin v. W.L. Haley & Co.*, 634 S.W.3d 16, 27 (Tenn. App. 2019), does not hold that a manifest physical injury would be required. *Id.* Plaintiffs offer *Laxton v. Orkin Exterminating Co.*, where the

Tennessee Supreme Court allowed a claim for medical monitoring despite negative test results, in support of its argument. 639 S.W.2d 431, 434 (Tenn. 1982). *Id.*

Neither case provided by the parties is dispositive of this issue. Respiromics's case, *City of Franklin v. W.L. Haley & Co.*, is of limited applicability because that case addressed recovery for economic losses under the Tennessee Products Liability Act, rather than the pleading requirements of the state statute. 634 S.W.3d at 27. Although the Court of Appeals of Tennessee recognized that "without a claim for personal injury or property damage, no claim may lie under the Products Liability Act," the court did not address whether claims of subcellular injury qualify as a personal injury. *Id.* Similarly, Plaintiffs' case, *Laxton v. Orkin Exterminating Co.*, addresses medical monitoring in a common law negligence claim rather than a claim arising under the Tennessee Products Liability Act. 639 S.W.2d at 434.

Consistent with the determination that physical injury in the form of physiological changes and subcellular harm suffices under other state product liability acts, it will be recommended that the Court deny Respiromics's motion to dismiss Plaintiffs' claims arising under the Tennessee Products Liability Act.

vii. Washington

Respiromics asserts that medical monitoring is only available under the Washington Products Liability Act if Plaintiffs demonstrate traditional elements of liability, including present physical injury. Supp. Br. (ECF No. 1352) at 36-37.

Respironics relies on *Duncan v. Nw. Airlines*, 203 F.R.D. 601, 609 (W.D. Wash. 2001). *Id.* at 37. Plaintiffs assert that under the Washington Products Liability Act, “[h]arm includes any damages recognized by the courts of this state” and that Plaintiffs’ allegations regarding subcellular injury or physiological damages satisfy that standard. *Duncan v. Nw. Airlines*, 203 F.R.D. 601, 609 (W.D. Wash. 2001). Opp. Br. (ECF No. 1634) at 58. Plaintiffs further aver that the cases cited by Respironics do not address the level or type of injury required under the statute. *Id.* at fn. 20 (citing *Steele v. Organon, Inc.*, 716 P.2d 920, 922 (Wash. App. 1986); *Hofstee v. Dow*, 36 P.3d 1073, 1076 (Wash. App. 2001)). Consistent with the determination that physical injury in the form of physiological changes and subcellular harm suffices under other state product liability acts, it will be recommended that the Court deny Respironics’s motion to dismiss Plaintiffs’ claims arising under the Washington Products Liability Act.

VIII. CONCLUSION

For the foregoing reasons set forth in this Report and Recommendation, it is recommended that the Court grant in part and deny in part Respiromics's motion to dismiss Plaintiffs' Second Amended Medical Monitoring Complaint. In accordance with Fed. R. Civ. P. 53(f)(2), objections to or requests for modification of this Report must be submitted within twenty-one days of today.

Dated: September 28, 2023

/s Thomas I. Vanaskie
Hon. Thomas I. Vanaskie (Ret.)
Special Master

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED)
CPAP, BI-LEVEL PAP, AND)
VENTILATOR PRODUCTS)
LITIGATION) Master Docket: Misc. No. 21-
)
) MDL No. 3014
This Document Relates to: All Actions)
)
)
)

**RECOMMENDATION ON THE MOTION OF DEFENDANT PHILIPS RS
NORTH AMERICA LLC TO DISMISS PLAINTIFFS' AMENDED
MASTER LONG FORM AND SHORT FORM COMPLAINTS FOR
PERSONAL INJURIES AND DAMAGES**

For the foregoing reasons provided in the attached Report on Defendant Philips RS North America LLC's Motion to Dismiss the Consolidated Second Amended Class Action Complaint for Medical Monitoring (ECF No. 1341), it is recommended that the Court grant the following:

1. Respiration's motion to dismiss the medical monitoring claims asserted under the laws of Arizona, Arkansas, Colorado, Connecticut, Delaware, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Maine, Minnesota, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North

Carolina, Ohio, Oklahoma, Oregon, Puerto Rico, Rhode Island, South Carolina, Texas, Virginia, and Washington (**COUNT IV**).

In all other respects, it is recommended the remaining aspects of the Motion be denied.

September 28, 2023

Date

/s/ Thomas I. Vanaskie

Hon. Thomas I. Vanaskie (Ret.)

Special Master